Complete Summary

GUIDELINE TITLE

Preventing tetanus, diphtheria, and pertussis among adults: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and Recommendation of ACIP, supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for Use of Tdap Among Health-Care Personnel.

BIBLIOGRAPHIC SOURCE(S)

Kretsinger K, Broder KR, Cortese MM, Joyce MP, Ortega-Sanchez I, Lee GM, Tiwari T, Cohn AC, Slade BA, Iskander JK, Mijalski CM, Brown KH, Murphy TV, Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices, Healthcare Infection Control Practices Advisory Committee. Preventing tetanus, diphtheria, and pertussis among adults: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine recommendations of the ACIP. MMWR Recomm Rep 2006 Dec 15;55(RR-17):1-37. [236 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Tetanus
- Diphtheria
- Pertussis

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Hospitals
Nurses
Pharmacists
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To review pertussis, tetanus and diphtheria vaccination policy in the United States
- To describe the clinical features and epidemiology of pertussis among adults
- To summarize the immunogenicity, efficacy, and safety data of a tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap)
- To present recommendations for the use of Tdap among adults aged 19 to 64 years

TARGET POPULATION

Adults aged 19 to 64 years who have never received a dose of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap), including adults in the general population, adults who have or who anticipate close contact with infants, and health care personnel

INTERVENTIONS AND PRACTICES CONSIDERED

Vaccination with the tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap; ADACEL®)

- Single dose as a booster in place of adult tetanus and diphtheria toxoids vaccine (Td)
- Along with tetanus immune globulin (TIG) as prophylaxis in wound management (in place of Td if not previously vaccinated with Tdap)
- As single dose in Td series for persons with incomplete or unknown history of tetanus, diphtheria, or pertussis vaccination

MAJOR OUTCOMES CONSIDERED

- Incidence of pertussis
- Rates of pertussis transmission
- Morbidity associated with pertussis
- Side effects of vaccination
- Cost-benefit and cost-effectiveness of vaccination

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-Benefit and Cost-Effectiveness Analyses of Adult Tdap Vaccination

Results of two economic evaluations that examined adult vaccination strategies for pertussis varied. A cost-benefit analysis in 2004 indicated that adult pertussis vaccination would be cost-saving. A cost-effectiveness analysis in 2005 indicated that adult pertussis vaccination would not be cost-effective.

To address these discrepancies, the adult vaccination strategy was re-examined using the cost-effectiveness study model. The updated analysis estimated the cost-effectiveness of vaccinating adults aged 20 to 64 years with a single tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) booster and explored the impact of incidence and severity of disease on cost-effectiveness. Costs, health outcomes, and cost-effectiveness were analyzed for a U.S. cohort of approximately 166 million adults aged 20 to 64 years over a 10-year period. The revised analysis assumed an incremental vaccine cost of $20 on the basis of updated price estimates of tetanus and diphtheria toxoids vaccine (Td) and Tdap in the private and public sectors, an incidence of adult pertussis ranging from 10 to 500 per 100,000 population, and vaccine delivery estimates ranging from 57 to 66% among adults on the basis of recently published estimates.

The programmatic cost of a one-time adult vaccination strategy would be $2.1 billion. Overall, the net cost of the onetime adult vaccination program ranged from $0.5 to $2 billion depending on disease incidence. The cost per case prevented ranged from $31,000 per case prevented at an incidence of 10 per 100,000 population to $160 per case prevented at an incidence of 500 per 100,000 (see Table 12 in the original guideline document). The cost per quality adjusted life years (QALY) saved ranged from "dominated" (where "No vaccination" is preferred) at 10 per 100,000 population to $5,000 per QALY saved at 500 per 100,000 population. On the basis of a benchmark of $50,000 per QALY saved, an adult vaccination program became cost-effective when the incidence exceeded 120 per 100,000 population. When adjustments were made for severity of illness at high disease incidence, little impact was observed on the overall cost-effectiveness of a vaccination program.

Similar results were obtained when program costs and benefits were analyzed over the lifetime of the adult cohort for the one-time and decennial booster strategies.

Cost-Benefit of Vaccinating Health-Care Personnel (HCP) with Tdap

By vaccinating HCP with Tdap and reducing the number of cases of pertussis among HCP, hospitals will reduce the costs associated with resource-intensive hospital investigations and control measures (e.g., case/contact tracking, postexposure prophylaxis, and treatment of hospital acquired pertussis cases). These costs can be substantial.

See the original guideline document for a full discussion of the cost-benefit of vaccinating health-care personnel with Tdap.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The following recommendations for the use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) (ADACEL®) are intended for adults aged 19 to 64 years who have not already received a dose of Tdap. Tdap is licensed for a single use only; prelicensure studies on the safety or efficacy of subsequent doses were not conducted. After receipt of a single dose of Tdap, subsequent doses of tetanus and diphtheria toxoid-containing vaccines should follow guidance from previously published recommendations for the use of tetanus and diphtheria toxoids vaccine (Td) and tetanus toxoid vaccine (TT) ("Diphtheria, tetanus, and pertussis," 1991). Adults should receive a decennial booster with Td beginning 10 years after receipt of Tdap ("Diphtheria, tetanus, and pertussis," 1991). Recommendations for the use of Tdap (ADACEL® and BOOSTRIX®) among adolescents are described elsewhere (Broder et al., 2006). BOOSTRIX® is not licensed for use in adults.

1. **Routine Tdap Vaccination**

1-A. Recommendations for Use

1. *Routine use*: Adults aged 19 to 64 years should receive a single dose of Tdap to replace a single dose of tetanus and diphtheria toxoids vaccine (Td) for active booster vaccination against tetanus, diphtheria, and pertussis if they received their last dose of Td ≥10 years earlier. Replacing 1 dose of Td with Tdap will reduce the morbidity associated with pertussis in adults and might reduce the risk for transmitting pertussis to persons at increased risk for pertussis and its complications.
2. *Short interval between Td and Tdap*: Intervals <10 years since the last Td may be used to protect against pertussis. Particularly in settings with increased risk for pertussis or its complications, the benefit of using a single dose of Tdap at an interval <10 years to protect against pertussis generally outweighs the risk for local and systemic reactions after vaccination. The safety of an interval as short as approximately 2 years between Td and Tdap is supported by a Canadian study; shorter intervals may be used (see "Safety Considerations for Adult Vaccination with Tdap" in the original guideline document). For adults who require tetanus toxoid-containing vaccine as part of wound

management, a single dose of Tdap is preferred to Td if they have not previously received Tdap (see "Tetanus Prophylaxis in Wound Management" below).

3. *Prevention of pertussis among infants aged <12 months by vaccinating their adult contacts*: Adults who have or who anticipate having close contact with an infant aged <12 months (e.g., parents, grandparents aged <65 years, child-care providers, and health-care personnel [HCP]) should receive a single dose of Tdap at intervals <10 years since the last Td to protect against pertussis if they have not previously received Tdap. Ideally, these adults should receive Tdap at least 2 weeks before beginning close contact with the infant. An interval as short as 2 years from the last dose of Td is suggested to reduce the risk for local and systemic reactions after vaccination; shorter intervals may be used.

   Infants aged <12 months are at highest risk for pertussis-related complications and hospitalizations compared with older age groups. Young infants have the highest risk for death. Vaccinating adult contacts might reduce the risk for transmitting pertussis to these infants (see "Infant Pertussis and Transmission to Infants" in the original guideline document). Infants should be vaccinated on-time with pediatric diphtheria and tetanus toxoids, acellular pertussis antigens (DTaP) ("Pertussis vaccination," 1997; CDC, "Recommended childhood and adolescent immunization schedule," 2006).

   When possible, women should receive Tdap before becoming pregnant. Approximately half of all pregnancies in the United States are unplanned (Henshaw, 1998). Any woman of childbearing age who might become pregnant is encouraged to receive a single dose of Tdap if she has not previously received Tdap (see "Vaccination During Pregnancy" below).

   Women, including those who are breastfeeding, should receive a dose of Tdap in the immediate postpartum period if they have not previously received Tdap. The postpartum Tdap should be administered before discharge from the hospital or birthing center. If Tdap cannot be administered before discharge, it should be administered as soon as feasible.

4. *Health-Care Personnel**: HCP in hospitals or ambulatory care settings** who have direct patient contact should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap. Although Td booster doses are routinely recommended at an interval of 10 years, an interval as short as 2 years from the last dose of Td is recommended for the Tdap dose among these HCP. These HCP include but are not limited to physicians, other primary care providers, nurses, aides, respiratory therapists, radiology technicians, students (e.g., medical, nursing, and other), dentists, social workers, chaplains, volunteers, and dietary and clerical workers.

   * Recommendations for use of Tdap among HCP wee reviewed and are supported by the members of the Healthcare Infection Control Practices Advisory Committee (HICPAC).

** Hospitals, as defined by the Joint Commission on Accreditation of Healthcare Organizations, do not include long-term–care facilities such as nursing homes, skilled-nursing facilities, or rehabilitation and convalescent care facilities. Ambulatory-care settings include all outpatient and walk-in facilities.

Other HCP (i.e., not in hospitals or ambulatory care settings or without direct patient contact) should receive a single dose of Tdap to replace the next scheduled Td according to the routine recommendation at an interval no greater than 10 years since the last Td. They are encouraged to receive the Tdap dose at an interval as short as 2 years following the last Td.

Vaccinating HCP with Tdap will protect them against pertussis and is expected to reduce transmission to patients, other HCP, household members, and persons in the community. Priority should be given to vaccination of HCP who have direct contact with infants aged <12 months (see "Prevention of pertussis among infants aged <12 months by vaccinating their adult contacts" above).

Hospitals and ambulatory-care facilities should provide Tdap for HCP and use approaches that maximize vaccination rates (e.g., education about the benefits of vaccination, convenient access, and the provision of Tdap at no charge) (see Implementing a Hospital Tdap Program in the section of the guideline summary entitled "Description of the Implementation Strategy"). Tdap is not licensed for multiple administrations. After receipt of Tdap, HCP should receive Td or tetanus toxoid vaccine (TT) for booster immunization against tetanus and diphtheria according to previously published guidelines ("Diphtheria, tetanus, and pertussis," 1991).

1-B. Dosage and Administration

The dose of Tdap is 0.5 mL, administered intramuscularly (IM), preferably into the deltoid muscle.

1-C. Simultaneous Vaccination with Tdap and Other Vaccines

If two or more vaccines are indicated, they should be administered during the same visit (i.e., simultaneous vaccination). Each vaccine should be administered using a separate syringe at a different anatomic site. Certain experts recommend administering no more than two injections per muscle, separated by at least 1 inch. Administering all indicated vaccines during a single visit increases the likelihood that adults will receive recommended vaccinations (Kroger et al., 2006).

1-D. Preventing Adverse Events

The potential for administration errors involving tetanus toxoid-containing vaccines and other vaccines is well documented (Graham et al., 1981; Institute for Safe Medication Practices, 2003; CDC, 2004). Pediatric DTaP vaccine formulations should not be administered to adults. Attention to proper vaccination technique, including use of an appropriate needle length and

standard routes of administration (i.e., IM for Tdap) might minimize the risk for adverse events (Kroger et al., 2006).

1-E. Record Keeping

Health-care providers who administer vaccines are required to keep permanent vaccination records of vaccines covered under the National Childhood Vaccine Injury Compensation Act; the Advisory Committee on Immunization Practices (ACIP) has recommended that this practice include all vaccines (Kroger et al., 2006). Encouraging adults to maintain a personal vaccination record is important to minimize administration of unnecessary vaccinations. Vaccine providers can record the type of the vaccine, manufacturer, anatomic site, route, and date of administration and name of the administering facility on the personal record.

2. Contraindications and Precautions for Use of Tdap

2-A. Contraindications

- Tdap is contraindicated for persons with a history of serious allergic reaction (i.e., anaphylaxis) to any component of the vaccine. Because of the importance of tetanus vaccination, persons with a history of anaphylaxis to components included in any Tdap or Td vaccines should be referred to an allergist to determine whether they have a specific allergy to tetanus toxoid and can safely receive TT vaccinations.
- Tdap is contraindicated for adults with a history of encephalopathy (e.g., coma or prolonged seizures) not attributable to an identifiable cause within 7 days of administration of a vaccine with pertussis components. This contraindication is for the pertussis components, and these persons should receive Td instead of Tdap.

2-B. Precautions and Reasons to Defer Tdap

A precaution is a condition in a vaccine recipient that might increase the risk for a serious adverse reaction (Kroger et al., 2006). The following are precautions for Tdap administration. In these situations, vaccine providers should evaluate the risks for and benefits of administering Tdap.

- Guillain-Barré syndrome $\leq$6 weeks after previous dose of a tetanus toxoid-containing vaccine. If a decision is made to continue vaccination with tetanus toxoid, Tdap is preferred to Td if otherwise indicated.

Tdap vaccination should generally be deferred during the following situations:

- Moderate or severe acute illness with or without fever. Defer Tdap vaccination until the acute illness resolves.
- Unstable neurologic condition (e.g., cerebrovascular events and acute encephalopathic conditions) (see "Safety Considerations for Adult Vaccination with Tdap" in the original guideline document for a discussion of neurological conditions).*

* For adolescents, any progressive neurologic disorder (including progressive encephalopathy) is considered a precaution for receipt of Tdap. For adults, progressive neurologic disorders are considered precautions only if the condition is unstable (Broder et al., 2006).

- History of an Arthus reaction following a previous dose of a tetanus toxoid-containing and/or diphtheria toxoid-containing vaccine, including meningococcal conjugate vaccine (MCV4) (see "Safety Considerations for Adult Vaccination with Tdap" in the original guideline document for description of Arthus reaction). Vaccine providers should review the patient's medical history to verify the diagnosis of Arthus reaction and can consult with an allergist or immunologist. If an Arthus reaction was likely, vaccine providers should consider deferring Tdap vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing and/or diphtheria toxoid-containing vaccine was received. If the Arthus reaction was associated with a vaccine that contained diphtheria toxoid without tetanus toxoid (e.g., MCV4), deferring Tdap or Td might leave the adult inadequately protected against tetanus. In this situation, if the last tetanus toxoid-containing vaccine was administered >10 years earlier, vaccine providers can obtain a serum tetanus antitoxin level to evaluate the need for tetanus vaccination (tetanus antitoxin levels $\geq$0.1 IU/ mL are considered protective) or administer TT.

2-C. Not Contraindications or Precautions for Tdap

The following conditions are not contraindications or precautions for Tdap, and adults with these conditions may receive a dose of Tdap if otherwise indicated. The conditions in italics are precautions for pediatric DTP/DTaP but are not contraindications or precautions for Tdap vaccination in adults ("Pertussis vaccination," 1997).

- *Temperature $\geq$105 degrees F ($\geq$40.5 degrees C) within 48 hours after pediatric DTP/DTaP not attributable to another cause*
- *Collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours after pediatric DTP/DTaP*
- *Persistent crying lasting $\geq$3 hours, occurring within 48 hours after pediatric DTP/DTaP*
- *Convulsions with or without fever, occurring within 3 days after pediatric DTP/DTaP*
- Stable neurologic disorder, including well-controlled seizures, a history of seizure disorder that has resolved, and cerebral palsy (See section, "Safety Considerations for Adult Vaccination with Tdap" in the original guideline document)
- Brachial neuritis
- Immunosuppression, including persons with human immunodeficiency virus (HIV). The immunogenicity of Tdap in persons with immunosuppression has not been studied and could be suboptimal.
- Breastfeeding
- Intercurrent minor illness
- Use of antimicrobials
- History of an extensive limb swelling (ELS) reaction following pediatric DTP/DTaP or Td that was not an Arthus hypersensitivity reaction (see

"Safety Considerations for Adult Vaccination with Td" section in the original guideline document for descriptions of ELS and Arthus reactions).

3. **Special Situations for Tdap Use**

3-A. Pertussis Outbreaks and Other Settings with Increased Risk for Pertussis or its Complications

During periods of increased community pertussis activity or during pertussis outbreaks, vaccine providers might consider administering Tdap to adults at an interval <10 years since the last Td or TT if Tdap was not previously received (see "Spacing and Sequencing of Vaccines Containing Tetanus Toxoid, Diphtheria Toxoid, and Pertussis Antigens" in the original guideline document). Postexposure chemoprophylaxis and other pertussis control guidelines, including guidelines for HCP, are described elsewhere (see "Management of Exposed Persons in Settings with Nosocomial Pertussis" in the original guideline document) (Schrag et al., 2003; "Immunization of health-care workers," 1997; American Academy of Pediatrics [AAP], 2006). The benefit of using a short interval also might be increased for adults with comorbid medical conditions (see "Clinical Features and Morbidity Among Adults with Pertussis" in the original guideline document).

3-B. History of Pertussis

Adults who have a history of pertussis generally should receive Tdap according to the routine recommendation. This practice is preferred because the duration of protection induced by pertussis is unknown (waning might begin as early as 7 years after infection [Wendelboe et al., 2005]) and because the diagnosis of pertussis can be difficult to confirm, particularly with tests other than culture for *Bordetella pertussis*. Administering pertussis vaccine to persons with a history of pertussis presents no theoretical safety concern.

3-C. Tetanus Prophylaxis in Wound Management

ACIP has recommended administering tetanus toxoid-containing vaccine and tetanus immune globulin (TIG) as part of standard wound management to prevent tetanus (see Table below) ("Diphtheria, tetanus, and pertussis," 1991). Tdap is preferred to Td for adults vaccinated $\geq$5 years earlier who require a tetanus toxoid-containing vaccine as part of wound management and who have not previously received Tdap. For adults previously vaccinated with Tdap, Td should be used if a tetanus toxoid-containing vaccine is indicated for wound care. Adults who have completed the 3-dose primary tetanus vaccination series and have received a tetanus toxoid-containing vaccine <5 years earlier are protected against tetanus and do not require a tetanus toxoid-containing vaccine as part of wound management.

An attempt must be made to determine whether a patient has completed the 3-dose primary tetanus vaccination series. Persons with unknown or uncertain previous tetanus vaccination histories should be considered to have had no previous tetanus toxoid-containing vaccine. Persons who have not completed

the primary series might require tetanus toxoid and passive vaccination with TIG at the time of wound management (see Table below). When both TIG and a tetanus toxoid-containing vaccine are indicated, each product should be administered using a separate syringe at different anatomic sites. Adults with a history of Arthus reaction following a previous dose of a tetanus toxoid-containing vaccine should not receive a tetanus toxoid-containing vaccine until ≥10 years after the most recent dose, even if they have a wound that is neither clean nor minor. If the Arthus reaction was associated with a vaccine that contained diphtheria toxoid without tetanus toxoid (e.g., MCV4), deferring Tdap or Td might leave the adult inadequately protected against tetanus, and TT should be administered (see precautions for management options above). In all circumstances, the decision to administer TIG is based on the primary vaccination history for tetanus (see Table below).

Table. Guide to Tetanus Prophylaxis in Routine Wound Management Among Adults Aged 19 to 64 Years

Characteristic	Clean, minor wound		All other wounds*	
History of adsorbed tetanus toxoid (doses)	Tdap or Td**	TIG	Tdap or Td**	TIG
Unknown or <3	Yes	No	Yes	Yes
≥3	No***	No	No[#]	No

* Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns, and frostbite.

** Tdap is preferred to Td for adults who have never received Tdap. Td is preferred to TT for adults who received Tdap previously or when Tdap is not available. If TT and TIG are both used, Tetanus Toxoid Adsorbed rather than tetanus toxoid for booster use only (fluid vaccine) should be used.

***Yes, if ≥10 years since the last tetanus toxoid-containing vaccine dose.

Yes, if ≥5 years since the last tetanus toxoid-containing vaccine dose.

3-D. Adults with History of Incomplete or Unknown Tetanus, Diphtheria, or Pertussis Vaccination

Adults who have never been vaccinated against tetanus, diphtheria, or pertussis (no dose of pediatric DTP/DTaP/DT or Td) should receive a series of three vaccinations containing tetanus and diphtheria toxoids. The preferred schedule is a single dose of Tdap, followed by a dose of Td ≥4 weeks after Tdap and another dose of Td 6 to 12 months later (CDC, "Recommended adult immunization schedule," 2006). However, Tdap can substitute for any one of the doses of Td in the 3-dose primary series. Alternatively, in situations in which the adult probably received vaccination against tetanus and diphtheria but cannot produce a record, vaccine providers may consider serologic testing for antibodies to tetanus and diphtheria toxin to avoid unnecessary vaccination. If tetanus and diphtheria antitoxin levels are each ≥0.1 IU/mL, previous vaccination with tetanus and diphtheria toxoid vaccine is presumed, and a single dose of Tdap is indicated.

Adults who received other incomplete vaccination series against tetanus and diphtheria should be vaccinated with Tdap and/or Td to complete a 3-dose primary series of tetanus and diphtheria toxoid-containing vaccines. A single dose of Tdap can be used in the series.

3-E. Nonsimultaneous Vaccination with Tdap and Other Vaccines, Including MCV4

Inactivated vaccines may be administered at any time before or after a different inactivated or live vaccine, unless a contraindication exists (Kroger et al., 2006). Simultaneous administration of Tdap (or Td) and MCV4 (which all contain diphtheria toxoid) during the same visit is preferred when both Tdap (or Td) and MCV4 vaccines are indicated (Broder et al., 2006). If simultaneous vaccination is not feasible (e.g., a vaccine is not available), MCV4 and Tdap (or Td) can be administered using any sequence. It is possible that persons who recently received one diphtheria toxoid-containing vaccine might have increased rates for adverse reactions after a subsequent diphtheria-containing vaccine when diphtheria toxoid antibody titers remain elevated from the previous vaccination (see "Safety Considerations for Adult Vaccination with Tdap" in the original guideline document).

3-F. Inadvertent Administration of Tdap (BOOSTRIX®) or Pediatric DTaP

Of two licensed Tdap products, only ADACEL® is licensed and recommended for use in adults. BOOSTRIX® is licensed for persons aged 10–18 years and should not be administered to persons aged $\geq$19 years. Pediatric DTaP is not indicated for persons aged $\geq$7 years. To help prevent inadvertent administration of BOOSTRIX® or pediatric DTaP when ADACEL® is indicated, vaccine providers should review product labels before administering these vaccines; the packaging might appear similar. If BOOSTRIX® or pediatric DTaP is administered to an adult aged $\geq$19 years, this dose should count as the Tdap dose and the patient should not receive an additional dose of Tdap (ADACEL®). The patient should be informed of any inadvertent vaccine administration.

Both Tdap products are licensed for active booster immunization as a single dose; neither are licensed for multiple administrations. After receipt of Tdap, persons should receive Td for booster immunization against tetanus and diphtheria, according to previously published guidelines ("Diphtheria, tetanus, and pertussis," 1991). If a dose of Tdap is administered to a person who has previously received Tdap, this dose should count as the next dose of tetanus toxoid-containing vaccine.

3-G. Vaccination during Pregnancy

Recommendations for pregnant women will be published separately (CDC, "Prevention of tetanus," 2006). As with other inactivated vaccines and toxoids, pregnancy is not considered a contraindication for Tdap vaccination (Kroger et al., 2006). Pregnant women who received the last tetanus toxoid-containing vaccine during the preceding 10 years and who have not previously received Tdap generally should receive Tdap after delivery. In

situations in which booster protection against tetanus and diphtheria is indicated in pregnant women, the ACIP generally recommends Td. Providers should refer to recommendations for pregnant women for further information (Kroger et al., 2006; CDC, "Prevention of tetanus," 2006).

Because of lack of data on the use of Tdap in pregnant women, Sanofi Pasteur has established a pregnancy registry. Health-care providers are encouraged to report Tdap (ADACEL®) vaccination during pregnancy, regardless of trimester, to Sanofi Pasteur (telephone: 800-822-2463).

3-H. Adults Aged ≥65 Years

Tdap is not licensed for use among adults aged ≥65 years. The safety and immunogenicity of Tdap among adults aged ≥65 years were not studied during U.S. pre-licensure trials. Adults aged ≥65 years should receive a dose of Td every 10 years for protection against tetanus and diphtheria and as indicated for wound management ("Diphtheria, tetanus, and pertussis," 1991).

Research on the immunogenicity and safety of Tdap among adults aged ≥65 years is needed. Recommendations for use of Tdap in adults aged ≥65 years will be updated as new data become available.

Reporting of Adverse Events

As with any newly licensed vaccine, surveillance for rare adverse events associated with administration of Tdap is important for assessing its safety in large-scale use. The National Childhood Vaccine Injury Act of 1986 requires health-care providers to report specific adverse events that follow tetanus, diphtheria, or pertussis vaccination (http://vaers.hhs.gov/reportable.htm). All clinically significant adverse events should be reported to the Vaccine Adverse Events Reporting System (VAERS), even if causal relation to vaccination is not apparent. VAERS reporting forms and information are available electronically at http://www.vaers.org or by telephone (800-822-7967). Web-based reporting is available and providers are encouraged to report electronically at https://secure.vaers.org/VaersDataEntryintro.htm to promote better timeliness and quality of safety data.

Vaccine Injury Compensation

See the original guideline document for information about the Vaccine Injury Compensation Program (VICP).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The availability of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) for adults offers an opportunity to reduce the burden of pertussis in the United States. The primary objective of replacing a dose of adult tetanus and diphtheria toxoids vaccine (Td) with Tdap is to protect the vaccinated adult against pertussis. The secondary objective of adult Tdap vaccination is to reduce the reservoir of pertussis in the population at large, and thereby potentially 1) decrease exposure of persons at increased risk for complicated infection (e.g., infants), and 2) reduce the cost and disruption of pertussis in health-care facilities and other institutional settings.

POTENTIAL HARMS

Adverse Events associated with Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap)

- Pain at injection site
- Erythema
- Lymph node swelling
- Fever
- Chills
- Headache
- Generalized body ache
- Tiredness
- Nausea
- Vomiting
- Diarrhea
- Sore and/or swollen joints

See also "Precautions and Reasons to Defer Tdap" in the "Major Recommendations" section of this guideline.

CONTRAINDICATIONS

CONTRAINDICATIONS

- History of serious allergic reaction (i.e., anaphylaxis) to vaccine components.
- History of encephalopathy (e.g., coma, prolonged seizures) not attributable to an identifiable cause within 7 days of administration of a pertussis vaccine.

Refer to "Contraindications and Precautions of Use of Tdap" in the "Major Recommendations" section of this summary for further discussion.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This report will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of the discussion of off-label use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) in the following situations:

A. The interval between tetanus and diphtheria vaccine (Td) and Tdap might be shorter than the 5 years indicated in the package insert.
B. Progressive neurological disorders are not considered a contraindication as indicated in the package insert, and unstable neurological disorders (e.g., cerebrovascular events, acute encephalopathic conditions) are considered precautions and a reason to defer Tdap and/or Td.
C. Tdap may be used as part of the primary series for tetanus and diphtheria.
D. Inadvertent administration of Tdap and pediatric diphtheria and tetanus toxoids and acellular pertussis antigens (DTaP) is discussed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Routine Adult Tdap Vaccination

The introduction of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) for routine use among adults offers an opportunity to improve adult vaccine coverage and to offer protection against pertussis, tetanus, and diphtheria. Serologic and survey data indicate that U.S. adults are undervaccinated against tetanus and diphtheria, and that rates of coverage decline with increasing age. Maintaining seroprotection against tetanus and diphtheria through adherence to Advisory Committee on Immunization Practices (ACIP)-recommended boosters is important for adults of all ages. ACIP has recommended that adults receive a booster dose of tetanus toxoid-containing vaccine every 10 years, or as indicated for wound care, to maintain protective levels of tetanus antitoxin, and that adults with uncertain history of primary vaccination receive a 3-dose primary series. Every visit of an adult to a health-care provider should be regarded as an opportunity to assess the patient's vaccination status and, if indicated, to provide protection against tetanus, diphtheria, and pertussis. Nationwide survey data indicate that although only 68% of family physicians and internists who see adult patients for outpatient primary care routinely administer tetanus and diphtheria vaccine (Td) for health maintenance when indicated, 81% would recommend Tdap for their adult patients.

Vaccination of Adults in Contact with Infants

Vaccinating adults aged <65 years with Tdap who have or who anticipate having close contact with an infant could decrease the morbidity and mortality of pertussis among infants by preventing pertussis in the adult and thereby preventing transmission to the infant. Administration of Tdap to adult contacts at least 2 weeks before contact with an infant is optimal. Near peak antibody responses to pertussis vaccine antigens can be achieved with booster doses by 7 days postvaccination, as demonstrated in a study in Canadian children after receipt of diphtheria and tetanus toxoids, acellular pertussis antigens, and inactivated polio vaccine (DTaP-IPV) booster.

The strategy of vaccinating contacts of persons at high risk to reduce disease and therefore transmission is used with influenza. Influenza vaccine is recommended for household contacts and out-of-home caregivers of children aged 0 to 59 months, particularly infants aged 0 to 6 months, the pediatric group at greatest risk for influenza-associated complications. A similar strategy for Tdap is likely to be acceptable to physicians. In a 2005 national survey, 62% of obstetricians surveyed reported that obstetricians and adult primary-care providers should administer Tdap to adults anticipating contact with an infant, if recommended by ACIP and the American College of Obstetricians and Gynecologists (ACOG).

Protecting women with Tdap before pregnancy also could reduce the number of mothers who acquire and transmit pertussis to their infant. ACOG states that preconceptional vaccination of women to prevent disease in the offspring, when practical, is preferred to vaccination of pregnant women. Because approximately half of all pregnancies in the United States are unplanned, targeting women of child-bearing age before they become pregnant for a dose of Tdap might be the most effective strategy. Vaccinating susceptible women of childbearing age with measles, mumps, and rubella vaccine also is recommended to protect the mother and to prevent transmission to the fetus or young infant. Implementing preconception vaccination in general medical offices, gynecology outpatient care centers, and family-planning clinics is essential to ensure the success of this preventive strategy.

If Tdap vaccine is not administered before pregnancy, immediate postpartum vaccination of new mothers is an alternative. Rubella vaccination has been successfully administered postpartum. In studies in New Hampshire and other sites, approximately 65% of rubella-susceptible women who gave birth received MMR postpartum. In a nationwide survey, 78% of obstetricians reported that they would recommend Tdap for women during the postpartum hospital stay if it were recommended. Vaccination before discharge from the hospital or birthing center, rather than at a followup visit, has the advantage of decreasing the time when new mothers could acquire and transmit pertussis to their newborn. Other household members, including fathers, should receive Tdap before the birth of the infant as recommended.

Mathematical modeling can provide useful information about the potential effectiveness of a vaccination strategy targeting contacts of infants. One model evaluating different vaccine strategies in the United States suggested that vaccinating household contacts of newborns, in addition to routine adolescent Tdap vaccination, could prevent 76% of cases in infants aged <3 months. A second model from Australia estimated a 38% reduction in cases and deaths

among infants aged <12 months if both parents of the infant were vaccinated before the infant was discharged from the hospital.

Vaccination of Pregnant Women

ACIP has recommended Td routinely for pregnant women who received the last tetanus toxoid-containing vaccine ≥10 years earlier to prevent maternal and neonatal tetanus. Among women vaccinated against tetanus, passive transfer of antitetanus antibodies across the placenta during pregnancy protect their newborn from neonatal tetanus.

As with tetanus, antibodies to pertussis antigens are passively transferred during pregnancy; however, serologic correlates of protection against pertussis are not known. Whether passive transfer of maternal antibodies to pertussis antigens protects neonates against pertussis is not clear; whether increased titers of passive antibody to pertussis vaccine antigens substantially interfere with response to diphtheria and tetanus toxoids and acellular pertussis antigens (DTaP) during infancy remains an important question. All licensed Td and Tdap vaccines are categorized as Pregnancy Category C* agents by the U.S. Food and Drug Administration (FDA). Pregnant women were excluded from prelicensure trials, and animal reproduction studies have not been conducted for Td or Tdap. Td and TT have been used extensively in pregnant women, and no evidence indicates use of tetanus and diphtheria toxoids administered during pregnancy are teratogenic.

* Animal studies have documented an adverse effect, and no adequate and well-controlled studies in pregnant women have been conducted or no animal studies and no adequate and well-controlled studies in pregnant women have been conducted.

Implementing a Hospital Tdap Program

Infrastructure for screening, administering, and tracking vaccinations exists at occupational health or infection prevention and control departments in most hospitals and is expected to provide the infrastructure to implement Tdap vaccination programs. New personnel can be screened and vaccinated with Tdap when they begin employment. As Tdap vaccination coverage in the general population increases, many new health-care personnel (HCP) will have already received a dose of Tdap.

To achieve optimal Tdap coverage among personnel in health-care settings, health-care facilities are encouraged to use strategies that have enhanced HCP participation in other hospital vaccination campaigns. Successful strategies for hospital influenza vaccine campaigns have included strong proactive educational programs designed at appropriate educational and language levels for the targeted HCP, vaccination clinics in areas convenient to HCP, vaccination at worksites, and provision of vaccine at no cost to the HCP. Some health-care institutions might favor a tiered approach to Tdap vaccination, with priority given to HCP who have contact with infants aged <12 months and other vulnerable groups of patients.

Purchase and administration of Tdap for HCP is an added financial and operational burden for health-care facilities. A cost-benefit model suggests that the cost of a Tdap vaccination program for HCP is offset by reductions in investigation and

control measures for pertussis exposures from HCP, in addition to the anticipated enhancement of HCP and patient safety.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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Advisory Committee on Immunization Practices

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Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Education activity is available from the Centers for Disease Control and Prevention (CDC) Web site.

PATIENT RESOURCES

None available

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